



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,546	01/18/2002	Gregory A. Demopulos	OMER118473	6615
26389 7590 11/21/2007 CHRISTENSEN, O'CONNOR, JOHNSON, KINDNESS, PLLC 1420 FIFTH AVENUE SUITE 2800 SEATTLE, WA 98101-2347			EXAMINER YOUNG, MICAH PAUL	
			ART UNIT 1618	PAPER NUMBER
			MAIL DATE 11/21/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/031,546	Applicant(s) DEMOPULOS ET AL.	
	Examiner Micah-Paul Young	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38,39,44-51,53,60,73-76 and 81 is/are pending in the application.
- 4a) Of the above claim(s) 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39,44-51,53,73-76 and 81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/27/07 has been entered.

Election/Restrictions

2. Claim 60 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected claim 59, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1/24/05.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

Art Unit: 1618

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. Claims 38,39,44-51,53,73-76, and 81 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Pelletier et al (USPN 5,972,880 hereafter '880 in view of Hunziker (USPN 5,206,023 hereafter '023). The claims are drawn to method of inhibiting cartilage degradation in a joint comprising delivering to the joint a composition comprising two chondroprotective agents.
2. The '880 patent discloses a method of treating osteoarthritis comprising the administration of compounds that inhibit cartilage catabolism (abstract). The compounds include interleukin receptor antagonist (examples). The method of treatment includes an intra-articular injection of an interleukin 1 receptor antagonist (col. 3, lin. 5-20). The reference also establishes the connection between the biological effects of IL-1 and those of transforming growth factors beta. The IL-1 has been shown to modulate the effect of TGF beta on the body (col. 4, lin. 1-20). Though not explicitly disclosed, it can be seen that the compounds have a synergistic effect, regulating and modulating each other. Inhibiting IL-1 effects decrease tissue growth and the effects of TGF-beta.
3. The '023 patent teaches methods for the treatment and repair of defects of lesions in cartilage (abstract). The method includes the delivery via injection a composition comprising anabolic promoting compounds such as fibroblast growth factors, transforming growth factor betas (3,4,5 etc), insulin growth factor-4 (col. 4, lin. 49-64; col. 5, lin. 44-58, example 3; claims) and chemotactic agents such as tumor necrosis factors (col. 7, lin. 50-65). The growth factors are combined with other components in methods to treat defects in knee cartilage (examples). The concentrations of the injection can be modulated to fit the needs of th patient (example)

Art Unit: 1618

4. Since both '880 and '023 disclose compositions for the treatment of cartilage damage, it would be well within the level of skill in the art to combine them in order to provide an improved cartilage treatment composition. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *See In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). The combination of the interleukin -1 receptor antagonist with the anabolic compounds of '023 would modulate each other, and work toward a mutual cartilage preserving need.

5. With these things in mind one of ordinary skill in the art would recognize how the IL-receptor antagonist of the '880 would help modulate the effects of the growth factors of the '023 patent allowing them to increase production of proteoglycans without over producing and creating osteophytes causing osteoarthritis. The interleukin antagonist compounds would keep the growth factors in check while they promoted anabolic growth in the damaged cartilage. This combination would be obvious since an over growth of osteophytes is recognized as a contributor to osteoarthritis. This combination would have been obvious to one of ordinary skill in the art with an expected result of a regulating injection compound able to treat damaged cartilage while avoiding osteoarthritis.

Response to Arguments

6. Applicant's arguments with respect to claims 38,39,44-51,53,60,73-76 and 81 have been considered but are moot in view of the new ground(s) of rejection.

Art Unit: 1618

Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MP Young

Micah-Paul Young
Examiner
Art Unit 1618


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER